

### **DETAILED ACTION**

Applicant's arguments and terminal disclaimer filed on December 3, 2009 and February 5, 2010, has been received and entered. Applicants' amendments to the specification filed August 19, 2004 have been previously entered. Claims 1, 4-5, 7-13, 16-25 and 26 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of the invention of claims 1-26 (group I) filed September 18, 2006 was acknowledged. It was noted that applicants elected 2D-CD4 as species for examination in a supplementary response filed on 12/ 28/2006. Since elected species is found free of art, all other species of pathogens as set forth in claims 16-17, 22-24 are rejoined with this action.

Claims 1, 4-5, 7-13, 16-25 and 26 are under examination.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 12/3/2009 and 2/5/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 7,312,076 and 7,456,011, respectively have been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Withdrawn- Double Patenting***

Claims 1, 4-5, 7-13, 18-21, 25 and 26 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. US Patent 7,312,076 (application no 11/620,588). Applicants' terminal disclaimer dated December 3, 2009, has been accepted, therefore, instant rejections are rendered moot and hereby withdrawn.

Claims 1, 4-5, 9, 11-13, 18-21, 25 and 26 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 8-10 of copending Application No. 11/938044 in view of Boyd (US 6,193,982, IDS). Applicant's arguments, see page 4, filed 12/3/2009, with respect to provisional obviousness double patenting rejection over 11/938044 have been fully considered and are persuasive. The rejection of claims 1, 4-5, 9, 11-13, 18-21, 25 and 26 is hereby withdrawn because '044 has not been allowed.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mathew Hinsch February 3, 2010.

The application has been amended as follows:

***In the claims***

Claim 1 has been replaced with the following:

Claim 1: An isolated *Lactobacillus jensenii* bacterium comprising an expression cassette, the expression cassette comprising a promoter operably linked to polynucleotide encoding a signal sequence and a biologically-active polypeptide, wherein the biologically active polypeptide is expressed, is anchored to the cell wall of the *Lactobacillus* bacterium or is released from the *Lactobacillus* bacterium, and is linked to a heterologous carboxyl terminal cell wall targeting region and wherein the cell wall targeting region comprises sequence selected from group consisting of SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO: 7 in which LPQTG (SEQ ID NO:13) is replaced with LPQSG, LPQAG or LPQTA (SEQ ID NO:11, 12, 14, respectively) and SEQ ID NO: 8 in which LPQTG (SEQ ID NO:13) is replaced with LPQSG, LPQAG, or LPQTA (SEQ ID NO:11, 12 or 14, respectively), and wherein the biologically active protein binds to a pathogen when the biologically active protein is contacted with the pathogen.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: The declaration under 37 CFR 1.132 filed 02/04/2009 provides sufficient evidence that, at the time the invention was made, it was unpredictable to genetically engineer *L. jensenii* to express a desired biologically active protein. Additionally, prior art is silent with respect to cell wall targeting region comprising SEQ ID NO: 7, 8 or specific variants of

SEQ ID NO: 7 and 8 as claimed. Instant specification provides adequate guidance with respect to genetically engineer *L. jensenii* that express a biologically active protein.

***Conclusion***

Claims 1, 4-5, 7-13, 16-25 and 26 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/  
Primary Examiner, Art Unit 1632

Anoop Singh  
AU 1632